DOCKET NO.: UPN-5191 / L2091X PATENT

Application No.: 10/625,073 **Office Action Dated:** July 31, 2008

REMARKS

Upon entry of this amendment, claims 1, 3 to 14, 16 and 17 will be pending. Claim 15 is canceled herein, without prejudice. Claims 1 and 3 to 5 are under consideration. Claims 6 to 14, 16 and 17 are withdrawn as drawn to unelected species of the invention.

Claims 1, 5, 6, 8 to 14, 16 and 17 are amended to insert the structures that correspond to the recited Formulas. Applicants respectfully submit that this renders moot the rejection under Section 112, second paragraph. Withdrawal of the rejection is respectfully requested.

Claims 1 and 3 to 5 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly not enabled. Applicants respectfully traverse this rejection.

The present claims are directed to the use of known compounds that have previously been shown to function as TRANCE/RANK inhibitors (*see* PCT/US99/15062) for treating patients who have diseases characterized by bone loss. The methods comprise the step of administering to a patient an amount of one of the TRANCE/RANK inhibitors effective to inhibit osteoclastogenesis and/or osteoclast function. The Applicants show in the specification that known TRANCE/RANK inhibitors OPG and a peptidomimetic WP9QY both function to inhibit osteoclastogenesis.

It appears that the basis of the non-enablement rejection is that the presently claimed compounds are small molecules, not peptides or peptidomimetics, and that the Applicants have not shown that small molecule TRANCE/RANK inhibitors also function as inhibitors of osteoclastogenesis and/or osteoclast function. To address the Examiner's concerns, enclosed herewith pursuant to 37 C.F.R. § 1.132 is the Declaration of Dr. Ramachandran Murali, one of the inventors of the instant invention. As set forth in the Declaration, Dr. Murali states that five small molecule TRANCE/RANK inhibitors (including the compound I-A, which is represents the species elected for prosecution herein¹) were tested in TRAP assays as described in Example 2 of the application. The data show that these data produce a dose dependent reduction in osteoclast formation in the TRAP assay. Dr. Murali concludes from this data that small molecule TRANCE/RANK inhibitors, in particular, those of Formula I or Formula III as described in the instant application, are, like OPG and the peptidomimetic described in the specification, effective inhibitors of osteoclastogenesis.

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Identified as compound "TMT" of Formula I.

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In view of the Declarative evidence submitted herewith, Applicants respectfully submit that they have shown that TRANCE/RANK inhibitors like those claimed have been shown to have utility in the claimed methods, and accordingly request that the rejection under Section 112, first paragraph be withdrawn. Moreover, since it has been shown that the elected species is allowable, it is requested that the full scope of Applicants generic claims be considered.

Applicants believe that the claims are now in condition for allowance. Accordingly, and Notice of Allowability for all of pending claims 1, 3 to 14, 16 and 17 is respectfully requested.

Date: September 29, 2008 /S. Maurice Valla/ S. Maurice Valla

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